EFFECT OF SILDENAFIL ON ERECTILE DYSFUNCTION IN SPINAL CORD INJURED PATIENTS

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SUMMARY

Background: Erectile dysfunction is a preoccupying issue, just like motor and bladder disability, in spinal cord injured (SCI) patients. This is particularly so because of the increasing prevalence of paraplegic and tetraplegic subjects and the fact that these patients are younger, and sexually active.

Objective: To determine the effects of Sildenafil (Viagra®) on erectile dysfunction in SCI patients.

Methods: After medical ethics committee approval and informed patient consent, we conducted a prospective inquiry between January and March 2007 in 16 SCI patients who were under Sildenafil treatment for erectile dysfunction. An abridged version of the International Index of Erectile Function (IIEF-5) questionnaire was completed the patients.

Results: The mean age (range) of the patients was 32.75 yrs (21-53 yrs). The mean duration of their disability was 47.75 months (4 yr). Trauma was the etiology in 87.5% of the cases (44% were road accidents). 12/16 patients were paraplegics (10 above T10) and 4 were tetraplegics (1 above C4 and 3 below C5). The mean duration of sildenafil treatment was 18.75 months (17 days-7 yr). 70% of the patients were satisfied with their erection after treatment. However, 10/16 patients had concomitant treatment with alprostadil.

Conclusion: Sildenafil is a vasoactive drug which can be used as a simple, discrete and effective treatment for erectile dysfunction in SCI patients. This approach is compatible with the efforts to improve the quality of life and rehabilitation of these patients.

Keywords: paraplegia, spinal cord injury, erectile dysfunction, Sildenafil

INTRODUCTION

Care of spinal cord injured (SCI) patients is a major preoccupation regarding sexuality, motor and bladder dysfunctions. This is particularly so because of the increasing prevalence of paraplegic and tetraplegic subjects and the fact that these patients are younger, and sexually active. This increase in prevalence is directly related with the increase in life expectancy of these patients irrespective of the etiology. In fact, an inquiry conducted in France, in 2002, showed an incidence of 19.4/million inhabitants and a prevalence of 100-400/million regarding post trauma paraplegic and tetraplegic subjects.[1]

Erectile and ejaculation disorders in these patients require effective management in order to improve their social and familial rehabilitation. This preoccupation, shared by many research and healthcare teams has led, in the past years, to the use of vasoactive drugs like Sildenafil in view of improving the sexuality of patients with erectile dysfunction.[2, 3] The objective of this study was to determine the effects of Sildenafil on erectile dysfunction in SCI patients.

MATERIALS AND METHODS

The study was approved by the ethics committee of the University of Bordeaux. Informed patient consent was obtained prior to data collection. From January to March 2007, we conducted an inquiry in 16 SCI paraplegic and tetraplegic male patients who were either currently or previously admitted (2000-2007) at the Tour de Gassies Rehabilitation Center of Bordeaux/France. The inclusion criteria were male SCI patients who had been or currently treated by Sildenafil for erectile dysfunction. None SCI patients and those incapable of completing the questionnaire were excluded.

A questionnaire based on the concise version of the International Index of Erectile Function (IIEF-5) [4] was sent by ordinary mail to some patients while others received the questionnaire on site. This 5-item questionnaire has been validated by the National Institutes of Health Consensus Panel. Additionally we assessed patient satisfaction. The data was analyzed using the EPI info 2000 software. The results were expressed as mean and standard results were expressed as mean and standard deviation or range.

RESULTS

The mean age (range) of the patients was 32.75 yrs (21-53 yrs). The mean duration of their disability was 47.75 months (4 yr). Trauma was the etiology in 87.5% of the cases (44% were road accidents). 12/16 patients were paraplegics (10 above T10) and 4 were tetraplegics (1 above C4 and 3 below C5). The mean duration of sildenafil treatment was 18.75 months (17 days-7 yr). 70% of the patients were satisfied with their erection after treatment. However, 10/16 patients had concomitant treatment with alprostadil.

Table 1 Clinical characteristics of the study population (N=16)

Clinical Characteristic	Number of patients	Percent (%)
Duration of evolution		
< 12 months	5	31.25
1-5 yrs	6	37.50

The main characteristics of the study population are shown in Table 1. The prescription and distribution profiles of sildenafil are presented in Table 2. The main responses of the patients are shown in Table 3.

Table 2 Distribution and utilization of Sidenafil

Treatment	Number of patients	Percent (%)
Duration of Treatment		
<1 month	4	25
1-2 months	7	43.75
>12months	5	31.25
Prescription		
Physiotherapist	14	87.5
General practitioner	2	12.5

Table of 3: Erectile dysfunction according to the IIEF – 5 Classification

Items	Patients (n=16)	Percentage (%)
Q1. How do you rate your confidence that you could get and keep an erection?		
Not sure at all	10	62.5
Not very sure	3	18.75
Quite sure	2	12.5
Sure enough	1	6.25
Q2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (introduction of the penis into the vagina)?		
Never	2	12.25
Sometimes	2	12.25
Most times	3	18.75
Always	9	56.25
Q.3 during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?		
Never	2	12.25
A few times	8	50
Sometimes	3	18.75
Most times	2	12.25
Always	1	6.25
Q.4 During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?		
No attempt	2	12.25
Extremely difficult	2	12.25
Slightly difficult	4	25
Not difficult	8	50
Q5. When you attempted sexual intercourse, how often was it satisfactory for you?		
No attempt	2	12.25
Rare	1	6.25
Sometimes	2	12.25
Most times	2	12.25
Always	9	56.25

DISCUSSION

This study shows that sildenafil is an effective treatment of erectile dysfunction in SCI patients. The study population is comparable to other series including Tetrafigap,[1] Hulting[3] and Giuliano[6] with regard to young age and the fact that trauma was the major cause of the spinal cord lesion.[1, 7-9]

However the evolution period of the disorder was shorter than in Tetrafigap's series.

In this study, sildenafil was mainly prescribed by physiotherapists. These specialists are more concerned with the sexual disorders of SCI patients.

In fact, the French Society of Urology recommended this approach with the physiotherapist in the frontline.[10] However, the important role of general practitioners could not be totally excluded.

The response to the IIEF-5 questionnaire corroborate to previous studies of Giuliano and Hulting.[3,6] We used the IIEF-5 questionnaire because it is an auto evaluation form with a high degree of sensitivity and specificity in detecting the efficacy of treatment. It is not specifically designed for SCI patients. It consists of 5-intems derived from 15 of the complete version. This questionnaire takes into account four of the five areas of sexual function: erection, orgasm, sexual desire. [4] This concise version is simple and fast to use during consultation. The first item of the HEF-5 deals with the pretreatment status while the four other questions involve the post-treatment status of the patients.

We also added questions on global satisfaction so that the patients could compare their erectile conditions before and after sildenafil treatment. Despite the high satisfaction rate of our patients, 10/16 of them used other vasoactive drugs like alprostadil (edex). The main explanation for this was that sildenafil was not reimbursed by the French social welfare. The majority of the patients expressed their desire for the reimbursement of this drug in SCI patients. Patients who failed both the sildenafil and alprostadil were advised to consult our local multidisciplinary team of physiotherapists, neurosurgeons and anesthesiologists in order to determine whether they were suitable candidates for implantable sacral nerve stimulators. However, we did not assess the outcome of these consultations.

The results of this study are strictly in the hospital domain and could not be extrapolated to all SCI patients. Additionally, the sample size is too small to deduce any pertinent conclusions. However, our study provides further insight to the efficacy of Sildenafil on erectile dysfunction of SCI patients in corroboration with other studies. [2]

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